

ENHANCING THE VITALITY OF THE NATIONAL INSTITUTES OF HEALTH

ORGANIZATIONAL CHANGE TO MEET NEW CHALLENGES

Committee on the Organizational Structure of the
National Institutes of Health

Board on Life Sciences
National Research Council

Health Sciences Policy Board
Institute of Medicine

NATIONAL RESEARCH COUNCIL
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

THE NATIONAL ACADEMIES PRESS
Washington, D.C.
www.nap.edu

term of 6 years should be based on a positive external review of performance and the recommendations of the secretary of Health and Human Services.

Finally, the Committee believes that the special status granted NCI by the National Cancer Act should be reconsidered. The National Cancer Act of 1971, in addition to making the NCI director a Presidential appointee, created the President's Cancer Panel, composed of two scientists and one management specialist who provide progress reports to the President on the status of NCI's research. The act also replaced the National Cancer Advisory Council with an 18-member National Cancer Advisory Board composed of scientists and laypersons offering guidance and advice to NCI on all major initiatives. In addition, the act allows the NCI director to submit the institute's budget directly to the President, bypassing the NIH director in the process.

Because the President appoints the NCI director and the NCI budget bypasses the NIH director, it is possible that an unnecessary rift is created between the goals, vision, and leadership of NIH and those of NCI. NCI is by far and has been for some time the largest NIH institute (approximately 17% of the total NIH budget). It is not in the interests either of NIH's overall research and training programs, or of NCI, for the NIH director to have such limited authority. In addition, as the biological and cellular basis of cancer becomes more widely understood, the basic science underlying cancer research has direct implications for the etiology and progression of numerous other diseases, for example the cardiovascular, infectious, and even neurodegenerative diseases. Thus, for scientific and administrative reasons, NCI's special status should be reconsidered.

Recommendation 12: Reconsider the Status of the National Cancer Institute. Congress should examine the provisions of the National Cancer Act of 1971, particularly as they affect the authority of the NIH director to hire senior management and plan and coordinate the NIH budget and its programs in their entirety.

It should be noted that the requirement that NCI prepare a biyearly budget every year has some positive aspects in that the institute must undertake an annual strategic planning process. This useful exercise should not be dropped if NCI changes its administrative status as recommended above. Rather, all ICs should be required to develop an annual strategic plan, if they are not already doing so.

THE ADVISORY COMMITTEES

Like other federal science agencies, NIH makes extensive use of advisory committees of nonfederal scientists, health advocacy representatives, and others to ensure the best possible input of expertise and additional perspectives on the evaluation of programs and the development of policies and priorities. NIH had over 140 char-

tered advisory committees as of May 2002, more than any other federal agency.² The Public Health Service Act (PHSA) authorizes appropriate scientific and technical peer review of biomedical and behavioral research grant and cooperative agreement applications, research and development contracts, and research conducted at NIH through its advisory committees.

As described in greater detail in Chapter 2, NIH uses several types of advisory committees. Those groups can be located in the Center for Scientific Review (CSR) (the study sections) or the councils and boards created and used by individual institutes that choose not to use CSR for review of particular initiatives. National Advisory Councils and Boards perform the second level of peer review for research grant applications and offer advice and recommendations on policy and program development, program implementation, evaluation, and other matters of importance for the mission and goals of the IC; and they provide oversight of research conducted by IC intramural programs. The dual review system, which separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the resources to be allocated, permits a more objective evaluation than would result from a single level of review. NIH can make awards only if they have been approved by a national advisory council and the Secretary, and this helps to insulate NIH from pressure by a member of Congress or the administration to fund a particular project. The national advisory councils are also charged with providing advice on policies and programs, although several studies have found that members of the national advisory councils do not always feel they play a strong role in policymaking.³ The dual system of review provides the responsible NIH officials with advice about both scientific and societal values and needs (NIH, 1992b).⁴

In the appointment process, the President generally follows the recommendations of the Secretary, and the Secretary generally follows the advice of the NIH and IC directors in filling positions, although they add their own candidates from time to time. During the 1972-1974 period, when the Nixon Administration was trying to exert greater control over the NIH budget, there was conflict with the scientific community over the perceived politicization of the advisory committee appointment process; this issue re-emerges from time to time and is of current concern to the scientific and health advocacy communities (e.g., Bass et al., 2003). Moreover as a general matter, the success of any scientific enterprise is dependent on the encourage-

²They have 4,298 members, 75% of whom are members of initial review groups that evaluate applications for research funding. See overview and list of committees by appointing officials at <http://www1.od.nih.gov/cmo/about/index.html>.

³One study was conducted by the Institute of Medicine's Committee for a Study of the Organizational Structure of the National Institutes of Health in 1984. The other was conducted in the mid-1990s by a committee appointed by the NIH director. Neither report was made public. Copies are in the possession of the authors.

⁴Contracts are subjected to a similar peer review process, except that the second level of review is by senior IC staff.

ment of a wide variety of independent views. The Committee believes that it is essential that members be appointed to these advisory groups because of their ability to provide scientific or public health expertise to the review and approval of awards and policies. They should not be selected to advance political or ideological positions.

Several related issues emerged during the committee's deliberations with respect to NIH's advisory council system. First, there are important differences in the use and roles of the councils among ICs. Some councils are actively involved in setting institute goals and planning. In other cases, council actions are pro forma, with little advice or involvement sought from council by institute personnel. In still other cases, council members might also be grantees of the institute, and thus might feel constrained in expressing strong views or views that differ from those held by institute or program staff. Those issues highlight a missed opportunity for NIH. Advisory councils should routinely and consistently be consulted in the priority setting and planning processes of an institute. They should have active involvement in decisions regarding issuance of program announcements and requests for applications, which often reflect an institute's priorities and responses to emerging opportunities or demands. They should be working to ensure that the IC is held accountable in reaching its goals and communicating with the public. They should understand and be supportive of relevant trans-NIH initiatives. Finally, a criterion for review of every institute director should be how he or she interacts with and uses the expertise of his or her advisory council.

Under Section 406 of the PHSA, national advisory councils have up to 18 members appointed by the Secretary and nonvoting ex officio members from NIH and other federal agencies. Two-thirds of the appointed members are to be "from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and/or social sciences) relevant to the activities of the national research institute" and one-third "from the general public and shall include leaders in the fields of public policy, law, health policy, economics, and management." The Committee believes that the advisory council system should guarantee that ICs receive independent and qualified advice. Their members therefore must be reasonably free of conflicts of interest. In addition, if NIH is to achieve the goal of increased trans-NIH collaborations, it will be important to have cross-fertilization of institutes through advisory council membership. For example, it would be useful to have a cancer researcher (who receives funding from NCI or the American Cancer Society) serve on the council of the National Institute of Environmental Health Sciences or the National Institute of Child Health and Human Development.

Recommendation 13: Retain Integrity in Appointments to Advisory Councils and Reform Advisory Council Activity and Membership Criteria

- a. Appointments to advisory councils should be based solely on a person's

scientific or clinical expertise or his or her commitment to and involvement in issues of relevance to the mission of the institute or center.

b. The advisory council system should be thoroughly reformed across NIH to ensure that these bodies are consistently and sufficiently independent and are routinely involved in priority-setting and planning discussions. Councils should be effectively engaged in discussions with IC leadership to enhance accountability, facilitate translation of goals and activities to the scientific community and the public, and provide feedback to the IC director. To achieve sufficient independence and avoid conflicts of interest, a substantial proportion of a council's scientific membership should consist of persons whose primary source of research support is derived from a different institute or center or from outside NIH.

RESEARCH MANAGEMENT AND SUPPORT

Although administrative or overhead costs are often viewed in the eyes of those who would like to see more money going directly to research or training, at appropriate levels they are essential to the effectiveness of any organization, including those that sponsor research and training programs. Ultimately, the effectiveness of those responsible for the wide array of necessary administrative services depends on their leadership and management capabilities and their ability to keep administrative and overhead costs deployed in a manner that best supports the primary mission of the organization.

In the case of NIH, the resources for administrative and overhead functions flow through the Research Management and Support (RMS) budgets of the various units that make up NIH. These budgets, collectively, support all the administrative costs of operating NIH, including management of extramural activities (planning, receipt, peer review, and awards), some intramural research program costs, program development, priority setting, education and outreach, acquisition and maintenance of new information technology systems, professional development, and facility management. Given the structure and funding mechanisms of NIH, the aggregate RMS budget is composed of 27 budget line items, one from each of the 16 that receive separate budget appropriations from Congress. RMS is functionally distinguished from the NIH CEO, which is responsible for strategic leadership and receives a separate appropriation.

The administrative costs of NIH have been scrutinized regularly over the last few decades. In the early 1990s, congressional institutions were imposed that restricted efficiency and program growth of the RMS budget. A 1997 management study by Arthur Andersen (National Institutes of Health, 1997c) led to many management improvements, including

- Consolidation and improvement of purchasing programs
- Conversion of the mail service to an external performance-based contract